JAN 30 2009

510(k) SUMMARY K083040

510(k) Owner:	Alfa Wassermann Diagnostic Technologies, LLC 4 Henderson Drive West Caldwell, NJ 07006 Contact: Dennis Taschek Phone: 973-852-0177 Fax: 973-852-0237	
Date Summary Prepared:	October 13, 2008	
Device:	Trade Name: Classification: Common/Classification Name:	S-Test CRP Reagent cartridge Class II CRP: C-reactive protein test system (21 C.F.R. § 866.5270), Product code DCN
Predicate Device:	Manufacturers for analyzer/reagent system predicate is: Olympus AU640 Clinical Chemistry Analyzer CRP Latex Reagent (K961274)	
Device Description:	The S-Test C-Reactive Protein (CRP) reagent cartridge, used with the S40 Clinical Analyzer, is intended for quantitative *in vitro* diagnostic determination of CRP in serum or heparin plasma based on a photometric test measuring the agglutination that results when an antigen-antibody reaction occurs between CRP in the sample and anti-CRP mouse monoclonal antibody-coated latex.	
Intended Use:	The S-Test C-Reactive Protein Reagent Cartridge is intended for the quantitative determination of C-reactive protein concentration in serum or heparin plasma using the S40 Clinical Analyzer. Measurement of C-reactive protein aids in evaluation of the amount of injury to body tissues. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.	
Technological Characteristics:	The S-Test CRP Reagent is contained in a bi-reagent cartridge. Reagent 1 contains: 2-amino-2-hydroxymethyl-1,3-propanediol buffer (pH 8.5, 20 mmol/L). Reagent 2 contains: anti-human C-reactive mouse protein and monoclonal antibody-coated latex (2 mg/mL).	

Performance Data:	Performance data on S-Test CRP reagent included precision, accuracy, and sensitivity data. Precision: In testing at three CRP levels for 24 days, the within-run CV ranged from 1.1 to 3.0% and total CV ranged from 2.3 to 4.3%. In precision studies at three separate Physician Office Laboratory (POL) sites and in-house over five days, the within-run CV ranged from 1.0 to 7.5% and total CV ranged from 1.5 to 7.5%. Accuracy: In the correlation study, 95 samples with CRP values ranging from 5 to 91 mg/L were assayed on the S40 Clinical Analyzer using S-Test CRP (y) and a comparative method (x). Least-squares regression analysis yielded a correlation coefficient of 0.995, a standard error estimate of 2.1, a confidence interval slope of 0.961 to 1.004, and a confidence interval intercept of 0.4 to 1.6. In patient correlation studies at three separate POL sites using the S40 Clinical Analyzer and a comparative method, least-squares regression analysis yielded correlation coefficients of 0.997 to 0.998, standard error estimates of 1.5 to 1.6, confidence interval slopes of 0.934 to 0.986 and confidence interval intercepts of -0.1 to 2.1. Sensitivity: The detection limit was 2 mg/L. Serum vs. Plasma: A study was performed by running CRP determinations on 22 paired samples drawn from the same patients in serum and heparin plasma tubes. The use of plasma was confirmed in a matrix comparison study using the paired t-test for means: Range: 7 to 96 mg/L (serum), t-Statistic = 0.13, t-Critical value 2.08 at $\alpha = 0.05$, not statistically significant.
Conclusions:	Based on the foregoing data, the device is safe and effective. These data also indicate substantial equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Alfa Wassermann Diagnostic Technologies, LLC
c/o Mr. Dennis Taschek
Vice President, Reagent and Instrument Technology
4 Henderson Drive
West Caldwell, NY 07006

JAN 30 2009

Re: k083040
Trade Name: S-Test C-Reactive Protein (CRP)
Regulation Number: 21 CFR 866.5270
Regulation Name: C-reactive protein immuno-logical test system
Regulatory Class: Class II
Product Codes: DCN
Dated: January 8, 2009
Received: January 9, 2009

Dear Mr. Taschek:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indication for Use

510(k) Number (if known): K083040

Device Name: S-Test C-Reactive Protein (CRP)

Indication For Use: The S-Test C-Reactive Protein Reagent Cartridge is intended for the quantitative determination of C-reactive protein concentration in serum or heparin plasma using the S40 Clinical Analyzer. Measurement of C-reactive protein aids in evaluation of the amount of injury to body tissues. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

Prescription Use ✓ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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